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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte DAVID FARRAR, MALCOLM BROWN,
MICHAEL HALL, JOHN ERIC BRUNELLE,
NICHOLAS JOHN COTTON, ROD BERUBE, and
JOHN LIPCHITZ

Appeal 2013-007098
Application 11/668,497
Technology Center 3700

Before: EDWARD A. BROWN, JILL D. HILL, and LEE L. STEPINA,
Administrative Patent Judges.

STEPINA, *Administrative Patent Judge.*

DECISION ON APPEAL

STATEMENT OF THE CASE

David Farrar et al. (“Appellants”) appeal under 35 U.S.C. § 134 from a rejection of claims 1–4 and 6–29.¹ We have jurisdiction under 35 U.S.C. § 6(b).

¹ An oral hearing was conducted on November 17, 2016.

We AFFIRM.

CLAIMED SUBJECT MATTER

The claims are directed to a device for tissue repair and replacement, such as an orthopedic fixation device. Spec. 1 (Technical Field). Of the claims under appeal, claims 1, 8, 22, 23, 24, and 27 are independent. Claim 1, reproduced below, is illustrative of the claimed subject matter:

1. A device for tissue repair or replacement, comprising a discrete ceramic structure with pores and a ceramic material infiltrating the pores, *wherein the ceramic material further forms a substantially non-porous layer that substantially covers the device*, wherein the ceramic structure has a higher rate of in vivo degradation than the ceramic material so that, after implantation of the device, the ceramic structure degrades in vivo leaving a scaffold formed of the ceramic material, the scaffold having interconnected pores throughout the scaffold into which tissue can infiltrate.

Claims App. 2 (emphasis added).

REJECTION

Claims 1–4, 6–16, 22–24, and 27–29 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Final Act. 2.

OPINION

Appellants argue the claims under appeal as a group. Appeal Br. 7. We take claim 1 as representative, and the remaining claims under appeal stand or fall with claim 1. *See* 37 C.F.R. § 41.37(c)(1)(iv).

In finding that claims 1–4, 6–16, 22–24, and 27–29 read on an embodiment not taught in the Specification, the Examiner states, “[t]he limitations pertaining to the *ceramic* material further forming ‘a substantially non-porous layer that substantially covers the device’ (e.g., amended claim 1 at line 3) is neither described nor suggested in the original disclosure.” Final Act. 2.

Appellants contend that when the above-noted feature in claim 1 was added by amendment, Appellants “referred specifically to the portions of the specification as filed supporting the amendments to each claim.” Appeal Br. 9 (citing lines 14–17 of page 10 of the Amendment filed on September 26, 2011 (hereafter the “Amendment”)). The cited portion of the Amendment states “Claims 1, 3, 8, 14, 15, 22–24, and 27 have been amended to clarify the invention and to provide an antecedent basis. Support for these amendments can be found, for example, [in] FIGS. 4 and 4A, EXAMPLE 3, ¶¶ [0061]–[0063]. No new matter is introduced by these amendments.”² Amendment 10. Regarding this statement, Appellants contend, “[w]hen amended claims are supported by specific reference to the specification as filed, as here, general allegations such as ‘the application fails to describe or suggest the claimed invention’ are *not* a sufficient *reason* to make a prima

² The paragraph numbers provided by Appellants refer to paragraphs of U.S. Patent Application Publication No. 2007/0129810 (hereafter “the Printed Publication”), which is based on the present Application. *See* Spec. 12.

facie case of lack of written description.” Appeal Br. 10 (citing *In re Wertheim*, 541 F.2d 257, 263 (CCPA 1976)).

The purpose of the written description requirement in 35 U.S.C. § 112, first paragraph, is to “‘clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.’” *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc) (quoting *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1355, 1563 (Fed. Cir. 1991)). “[T]he test for sufficiency is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date.” *Ariad*, 598 F.3d at 1351 (citing *In re Gosteli*, 872 F.2d 1008, 1012 (Fed. Cir. 1989)). This test “requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art.” *Id.*

“Compliance with the written description requirement is essentially a fact-based inquiry that will ‘necessarily vary depending on the nature of the invention claimed.’” *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 963 (Fed. Cir. 2002) (quoting *Vas-Cath* at 1563). The “written description requirement is satisfied by the patentee’s disclosure of ‘such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention.’” *Id.* at 969 (quoting *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997)). “The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described.” *Id.* at 968 (citation omitted).

We do not agree with Appellants’ assertion that paragraphs 61–63 of the Printed Publication (Example 3) (*see* Specification 12) and Figures 4 and 4A support the claim feature in question. We find no disclosure of the use

of ceramic as a cover in any of these paragraphs or Figures. We find that paragraph 63 of the Printed Publication (corresponding to Specification: 12:13–21) provides information relating to the composition of the material used in the particular injection molding process described in Example 3, but does not describe that the covering material is a ceramic. Specifically, this portion of the Specification states:

Poly-glyconate B polymer was then injection molded into and around each plug. Standard melt processing temperatures were used, i.e., 410-435°F. Using different plugs, injection molding was conducted at pressures of 600, 800, 900 and 1000 psi, to examine the effect of pressure on filling of the pores. At each molding pressure, the interconnecting pores were filled throughout the entire plug, and a 0.050 inch layer of polymer was provided around the implant in the areas where there was a gap between the mold and plug due to the presence of the supporting ribs. The outer surface of the plug was exposed in the areas where the ribs contacted the plug. A plug formed using this procedure is shown diagrammatically in Figs. 4 and 4A.

Spec. 12:13–21 (emphases added). Thus, the procedure referred to in the above-noted portion of the Specification refers to the injection of *polymer*, and does not describe any covering of ceramic. Appellants do not identify any other description in the Specification indicating that what is depicted in Figures 4 and 4A is a ceramic covering. Thus, Appellants' initial attempt at identifying support for the claim feature in question was deficient, and the Examiner adequately established a prima facie case of lack of written description.

Appellants provide two Declarations under 37 C.F.R. § 1.132, one by Mr. Nicholas John Cotton (hereafter "Cotton Declaration") and another by Mr. David Farrar (hereafter "Farrar Declaration"), two of the named inventors in the present Application, in support of the assertion that the

claims are supported.³ Appellants contend “[t]he Examiner also erred by failing to consider the Rule 132 declarations by inventors Nicholas John Cotton (‘Cotton’) and David Farrar (‘Farrar’).” Appeal Br. 11. Appellants then quote a portion of a paragraph from the Final Action where the Examiner specifically addresses these Declarations. This paragraph states:

Applicant’s remarks have been considered. The Declarations submitted on May 21, 2012, are evidently copies of those filed on January 10, 2012. Applicant has still not provided any evidence for *ceramic bi-layers* allegedly being explicit in Applicant's original disclosure. The examiner thus has no choice but to conclude that said Declarations are based upon an erroneous premise, and if Inventor Farrar and Dr. Cotton did not have such misconceptions about the original specification supposedly teaching “ceramic-ceramic bi-layers” explicitly (e.g., Declaration under 37 CPR 1.132 of David Farrar: page 6, lines 1-2), then perhaps these individuals would have come to a conclusion similar to that of the examiner: that the claimed features in question are not described in the original disclosure sufficiently or with reasonable clarity. Other issues have been addressed in previous Office actions.

Final Act. 2:13–23 (emphasis added). Thus, the Examiner considered the Declarations and found them to be based on an erroneous premise, namely, that the Specification explicitly describes ceramic bi-layers.

The Cotton Declaration states:

I believe that in view of the many *examples* given in the specification of Farrar, including to ceramics, *ceramic bi-layers*, and differentially degrading rate combinations of ceramics, it

³ Mr. Cotton and Mr. Farrar do *not* make their statements as persons of ordinary skill in the art (which level Mr. Cotton and Mr. Farrar define in their Declarations), but rather, as persons “arguably more skilled than this defined level of ordinary skill in the pertinent art” who had “frequent and substantial contact with ... [persons] of ordinary skill in the pertinent art”. Cotton Declaration ¶ 7; Farrar Declaration ¶ 6.

was not necessary to have explicitly provided a complete example of the claimed ceramic - ceramic devices. I understand that under U.S. patent law and U.S. Patent Office rules it is well accepted that where a specification describes an invention in sufficient detail such that one of ordinary skill in the art can understand that the invention had to be, in fact, “invented,” and there is no need to actually make the device to prove invention.

Cotton Declaration ¶ 14 (emphasis added); *see also* ¶ 15. The Farrar Declaration states:

In my view, one of ordinary skill in the pertinent art in August, 2003, would have readily understood that the Farrar [sic] simply did not show an actual ceramic-ceramic embodiment because this was not necessary. The *explicit teaching* in the specification about *ceramic-ceramic bi-layers* wherein one layer has a faster rate of in vivo degradation than another layer, combined with the *explicitly taught exemplary embodiments of bi-layered devices* as example [sic] was sufficient to show invention of the claimed ceramic-ceramic device invention.

Farrar Declaration ¶ 14 (italics added, bolding and underlining omitted).

Although the Specification teaches a ceramic-ceramic embodiment in which one ceramic infiltrates another (*see, e.g., Spec. 10*), Appellants do not identify any disclosure in the Specification providing the alleged explicit teachings of ceramic-ceramic *bi-layers*. The Declarations opine that the feature in question is supported by the original disclosure (*see, e.g., Cotton Declaration ¶¶ 10, 13, Farrar Declaration ¶¶ 8, 11*), but the Declarations do not provide any persuasive evidence supporting that opinion. After considering the Cotton and Farrar Declarations in light of Appellants’ arguments and the original disclosure, we are not apprised of error in the Examiner’s treatment of the Declarations.

Appellants discuss the disclosure on pages 1–4, 10, and 12 of the Specification and state, “the only claim language that is not clearly explicitly

described in the specification as filed is ‘wherein the ceramic material further forms a substantially non-porous layer that substantially covers the device.’ This is the subject matter on which the Examiner is basing the written description rejections on appeal.” Appeal Br. 21–22.

Further, Appellants assert that the level of skill and knowledge in the art was high, the art was predictable, and therefore, “the level of disclosure in the [present Application] required to satisfy the written description requirement of 35 U.S.C. § 112, first paragraph, for the claimed invention is low.” Appeal Br. 23; *see also* Reply Br. 5–9. Appellants also contend that the original claims disclose injection molding of a ceramic material to provide infiltration of a ceramic structure. Appeal Br. 21. In this regard, Appellants state,

[F]or the claimed invention, the interior structure is a solid, porous, biodegradable ceramic and the flowable material is another, substantially non-porous ceramic material that only substantially covers the interior structure due to **inherent properties of the injection molding process** that leave[s] gaps in the covering (e.g., Appeal Brief, pg. 10, lns. 4–23, and pg. 18, lns. 7–9 and 17–18; in fact, *this description in the application as filed may explicitly describe the full scope of the claimed subject matter*) (Appeal Brief, pg. 21, lns. 9–27). And, as [a] (non-limiting) example of an illustrative embodiment of the application, fully explicitly described in the application, the interior structure is a solid, porous, biodegradable ceramic and the flowable material, substantially non-porous polymer that only substantially covers the interior structure due to **inherent properties of the injection molding process** that leave gaps in the covering (e.g., Example 3, pg. 12, lns. 4–12, and Figs 4 and 4A of the application) (Appeal Brief, pg. 21, lns. 14–27).

Reply Br. 13–14.

The Examiner finds that Appellants are “combining ([Appeal Brief] page 21, last paragraph) two distinct embodiments (one involving *polymer*

infiltration) that actually *are* disclosed, in an attempt to show support for the embodiment ‘*not* present in the application’.” Ans. 3.

We agree with the Examiner that Appellants disclose two separate embodiments in the Specification without providing sufficient connection between these embodiments to support the feature at issue here. Appellants’ references to the Specification do not establish persuasively that the injection molding process specifically described in Example 3 as providing a *polymer* layer around each ceramic plug (Spec. 12) is also disclosed as usable with the embodiment described in the Specification under the heading “**Devices including two ceramic components (Ceramic-Ceramic Systems)**” (Spec. 10), or any other embodiment providing a ceramic layer substantially covering the device. Appellants’ references to injection molding and to the original claims are unavailing in this regard. Original claim 18 recites: “[a] method of making a device for tissue repair or replacement, comprising forming a porous scaffold of a first component, and *infiltrating* the porous scaffold with a second component, wherein the first and second components comprise ceramics.” Spec. 18 (emphasis added). Thus, original claim 18 provides for infiltration with ceramic. Appellants provide no persuasive argument or evidence that infiltration of ceramic necessarily provides a covering, much less one that “substantially covers the device” as recited in claim 1 on appeal.

Original dependent claim 19 recites, “[t]he method of claim 18 wherein the scaffold is infiltrated with a sufficient amount of the second component to render the device substantially non-porous.” Spec. 18. Again, only infiltration, and no covering, is recited with respect to the first and second ceramic components. Original claim 20 requires that the second component is provided in the form of a slurry, and original independent

claim 22 requires first and second components comprising ceramics, but, again, neither claim provides any recitation of a covering. *Id.*

Original claim 21 depends from original claim 18 and recites, “[t]he method of claim 18 wherein the infiltrating step comprises *injection molding*.” *Id.* (emphasis added). Appellants provide no persuasive evidence or technical argument showing that a teaching of injection molding a ceramic corresponds to a teaching of providing a “ceramic material [that] forms a substantially non-porous layer that substantially covers the device” as recited in claim 1. In this regard, we note that Example 3 in Appellants’ Specification sets forth specific structure used in the injection molding process (used with a polymer) that results in the structure depicted in Figures 4 and 4A. *See* Spec. 12 (describing ribs positioned around the circumference of the inner plug and a gap between the mold and inner plug). None of this structure is discussed in Appellants’ disclosure with respect to injection molding a *ceramic*, much less that injection molding is used with a ceramic to create a layer substantially covering a device as recited in claim 1. Indeed, original claim 21 specifies that the injection molding is part of the *infiltration* step and is silent regarding the formation of any layer that covers another component.⁴ *Id.* Furthermore, Appellants provide no

⁴ Claim 1 recites “a discrete ceramic structure with pores and a ceramic material infiltrating the pores.” Claims App. 2. Claim 1 also recites that “the ceramic material further forms a substantially non-porous layer that substantially covers the device.” *Id.* Accordingly, we understand that the recited “ceramic material infiltrating the pores” does not inherently provide “a substantially non-porous layer that substantially covers the device” because these limitations are separately recited in claim 1. “Where a claim lists elements separately, ‘the clear implication of the claim language’ is that those elements are ‘distinct component[s]’ of the patented invention.” *Becton, Dickinson and Co. v. Tyco Healthcare Group, LP*, 616 F.3d 1249, 1254 (Fed. Cir. 2010).

persuasive explanation or evidence as to why injection molding a ceramic material, which claim 1 does not limit, would inherently result in the substantial covering recited in claim 1. Rather, Appellants' discussion of ceramic *infiltration* via injection molding and discussion of the specific structure used for providing the covering discussed in Example 3 demonstrate that injection molding does not inherently result in the structure recited in claim 1.

We have reviewed Appellants' Declarations, the Specification, and figures and considered all of Appellants' arguments. Weighing all the evidence provided, we agree with the Examiner's finding that claim 1 fails to comply with the written description requirement of 35 U.S.C. § 112, first paragraph. Claims 2–4, 6–16, 22–24, and 27–29 fall with claim 1.

DECISION

The Examiner's decision to reject claims 1–4, 6–16, 22–24, and 27–29 is affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a). *See* 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED